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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,554	09/18/2001	Charles S. Vann	ABI-0041	1610
27572	7590	05/25/2005	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			NAGPAUL, JYOTI	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/955,554	VANN ET AL.	
	Examiner	Art Unit	
	Jyoti Nagpaul	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 34-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,34-45,47,51 and 54 is/are rejected.
- 7) Claim(s) 46,48,49,52,53 and 55-57 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/22/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claims 44 and 45** are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: beads and the claimed apparatus (array of reagent dispensers, gate mechanism, first support, second support).

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. **Claims 1, 34-57** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-30 of U.S. Patent No. 6432719. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the patent claims differ by reciting an array having at least 100 reagent dispensers, where the dispensers are elongated containers and each having a longitudinally extending passageway configured to receive and hold a respective reagent when gate mechanism is in the closed position and in that the dispensers are configured to permit a respective reagent to move downward through passageway under the force of gravity. The instant claims recites an array of reagent dispensers, where the dispensers are elongated containers and each have a longitudinally extending passageway configured to receive and hold a respective reagent when gate mechanism is in the closed position and the dispensers are configured to permit a respective reagent to move downward through the passageway under the force of gravity in the dependent claims 35-36. It would have been obvious to one of the ordinary skill in this art at the time of the invention by applicant to employ an array having at least 100 reagent dispensers in order to increase high throughput of the process.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1,34-35,42-45,50-51,54** are rejected under 35 U.S.C. 102(b) as being anticipated by Astle (US 5525302).

Astle teaches an addressable array of reagent dispensers, a gate mechanism (146) at a lower outlet region of each dispenser, each gate mechanism being independently operable between an open condition permitting passage of a respective reagent through the outlet region and a closed condition whereat such passage is blocked. Astle further teaches a first support (126) disposed below the dispensing array, and a second support (124) having a holding area for receiving a plurality of receptacles (90), both positionable permitting placement of any selected target site of the holding area directly over the fixed target region (Column 7, Lines 14-60). It is also noted the "lower outlet region" limitation is not defined in the specification and is not necessarily interpreted to mean the distal end of the dispenser. The dispensers are elongated containers, each having a longitudinal extending passageway configured to receive and hold a respective reagent when gate mechanism (142, 146) is in the closed position. The device further comprises a rack/holding mount (40) having an array of holding cells being configured to removably support one of the containers (82) in a substantially upright fashion. (See Figure 5) The first and second supports are independently operable xy stages. (See Col.7, Lines 14-32) Astle recites, "the mechanism by which tubes/containers (82) may be selectively pinched to prevent fluid flow therethrough, the mechanism generally indicated by the reference numeral (140). Mechanism (140) includes an anvil (142) fixedly disposed with respect to frame (22) and a clamping frame (144) movable horizontally left and right.....Clamping frame (144) includes eight clamping bars, as at 146, orthogonally disposed with respect to the direction of movement of clamping frame (144), each of which clamping bars is

disposed to engage twelve of tubes (82) and clamp them against anvil (142) to thereby prevent fluid flow therethrough." (See Col. 7, Lines 34-44)

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 36-41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Astle.

Refer above for the teachings of Astle.

Astle fails to teach an array having at least about 100,1000, 10000 or 100,000 holding cells and the holding cells are disposed at an average density of at least about 3 or 4 holding cells per cm².

It would have been obvious to one of the ordinary skill in this art at the time of the invention by applicant to provide the system of Astle such that an array having at least about 100,1000, 10000 or 100,000 holding cells and the holding cells are disposed at an average density of at least about 3 or 4 holding cells per cm² in order to achieve high throughput analysis.

Allowable Subject Matter

9. **Claims 46, 48-49, 52-53 and 55-57** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

With respect to Claims 44-46, prior art does not teach or fairly suggest bead and plurality of sealed ampules wherein each ampule contains beads from the same or substantially identical lots.

With respect to Claims 48-49, prior art does not teach or fairly suggest a detection assembly having a field of view extending between dispenser outlet regions and second support, a radiation emitter that is mounted on first support at a region along one side of second support, and a radiation sensor.

With respect to Claims 52-53, prior art does not teach or fairly suggest a magnetic pinch valve having first and second magnets that are pivotally facing relation at a respective outlet region that are normally urged toward one another by magnetic forces so as to pivot magnets to the closed position and a release mechanism is an electromagnet positioned adjacent radiation-beam pathway.

With respect to Claims 55-57, prior art does not teach or fairly suggest a release mechanism is a rod adapted for motion from a retracted position to an extended position adjacent radiation-beam pathway and a guide member disposed for movement with first support to a position under any selected dispenser.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Nagpaul whose telephone number is 571-272-1273. The examiner can normally be reached on Monday thru Friday (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JN


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